A RANDOMIZED COMPARATIVE CLINICAL STUDY ON *APAMARGA PRATISARANIYA TEEKSHNA KSHAR*, LASER HEMORRHOIDOPEXY AND PILE SUTURE TECHNIQUE IN THE MANAGEMENT OF *ARDRA ARSHA* W.S.R. TO SECOND AND THIRD DEGREE INTERNAL HEMORRHOIDS

National Institute of Ayurveda,

Deemed To Be University (De-Novo)

Jaipur, Rajasthan

PROPOSED SYNOPSIS

FOR THE DEGREE OF

Ayurveda Vidyavaridhi (Ph.D.)

Scholar

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APPLICATION FOR REGISTRATION OF DISSERTATION

To
The Registrar,
National Institute of Ayurveda,
Deemed To Be University (De-Novo), Jaipur (Rajasthan) – 302002

Through: - Proper Channel

Subject: - Synopsis Submission of the Dissertation for registration in Ayurveda Vidyavaridhi (Ph.D.) program in the Department of Shalya Tantra.

Respected Sir,

With due regard, I am here by submitting the synopsis of my Dissertation along with other particulars for registration for the award of Ayurveda Vidyavaridhi (Ph.D.) in the Department of Shalya Tantra. The particulars are as follows: -

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Enrollment No.	Applied
Previous exam passed	M.S. (Ay.), Shalya Tantra
Institution	National Institute of Ayurveda, Deemed to be University, (De-Novo), Jaipur (Rajasthan)
Language of the Thesis	English, Sanskrit, Hindi
Proposed title of the Dissertation	A RANDOMIZED COMPARATIVE CLINICAL STUDY ON *APAMARGA PRATISARANIYA TEEKSHNA KSHAR*, LASER HEMORRHOIDOPEXY AND PILESUTURE TECHNIQUE IN THE MANAGEMENT OF *ARDRA ARSHA* W.S.R. TO SECOND AND THIRD DEGREE INTERNAL HEMORRHOIDS
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INTRODUCTION

Symptomatic anal cushions are termed as hemorrhoid which is one amongst common diseases involving anal region and can be correlated with *Arsha* found mentioned in Ayurveda text books. *Arsha* has been considered as a disease like an enemy for the person who suffers with the disease which is also considered a *Mahagad* meaning a disease which is difficult to treat or cause lot of sufferings to the patient. When we consider clinical presentation of hemorrhoids it is evident that patients suffer symptoms recurrently in most of the cases leading to multiple visits to anorectal clinics or general practitioners which justify the description of the disease as *Mahagad* in *Ayurveda*.

Abundant of Management options areavailable in Ayurvedic as well as contemporary science for Hemorrhoids disease, from conservative management to operative procedure. Lots of comparative study accessible in modern science but no anycomparative study conducts between surgical and Para-surgical procedure so we are not reached the final conclusion that which approached is best for the management of Hemorrhoid.

In Ayurveda science *Acharyas* mention that whole Ayurveda has divided into 8 branches. In which *Shayla Tantra* branch is most important for medicine as well as surgical management. *Sushruta*, the father of surgery and the author of *Sushruta Samhita* has mentioned four treatment modalities as perclinical condition for *Arsha* i.e. *Bheshaja Chikitsa* (Medical Treatment), *Kshar Karma* (Caustic Therapy), *Agnikarma* (Thermal Cautery) and *Shastra Karma* (Surgery). *Kshar Karma* is indicated in *Arsha* which are *Mridu, Prasrita, Avagada* and *Uchchhrita*. Apart from all modalities *Kshar Karma* is very effective, minimum invasive and easy Para-surgical treatment for second and third degree internal Hemorrhoids.

Modern science also said many conservative (Modification of sedentary life style, oral medications, local application), Para surgical (Sclerotherapy, Rubber Band Ligation, IRC, Diathermy Coagulation, Laser Hemorrhoidopexy) and surgical procedures (Hemorrhoidectomy, Pile Suture Technique and Stapled Hemorrhoidsopexy) in Hemorrhoids. All modalities are effective in surgical

practice but merit and demerit also present in each therapy so here we have planed of this comparative study in second and third-degree internal Hemorrhoids.

Application of *Apamarg Pratisaraniya Teekshna Kshar* in internal Hemorrhoids is very easy, safe, and bloodless with minimum complications, day care and effective procedure under local anesthesia. Laser Hemorrhoidopexy highly selective in second & third degree Hemorrhoids due to minimum invasive, lowest pain, day care and easy process under local anesthesia. Pile suture technique (Plication) of Hemorrhoids is also easy and safe procedure under local anesthesia but lower chance of risk of anal stricture in post-operative period.

This study compares efficacy of all technique's on same parameter of disease because no any study has conducted in Ayurveda sphere till now.

NEED OF THE STUDY

Nowadays abundant of surgical and Para-surgical approaches have developed for Hemorrhoids in current surgical practice. Our Ayurveda science also actively contribute many procedures for *Arsha* in *Sushruta Samhita* and many studies also conducted in various institutions on this disease but no any comparative data are available in contemporary as well as Ayurvedic science on these procedures i.e. *Apamaraga Pratisarniya Teekshna Kshar*, Laser Hemorrhoidopexy, Pile suture technique**.** After arrival of this data, maybe we will give better advise to our society for the management of this illness.

PREVIOUS WORK

National Institute of Ayurveda, Jaipur PGWorks

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- Dr.Nimba Ram-A comparative clinical study on sclerotherapy and *Apamarga Pratisaraniya Teekshna Kshar* in the management of *Ardra Arshas* W.S.R to first and second degree internal Hemorrhoid
- Dr. Ram Sinha- A comparative clinical study of *Nimba Pratisaraniya Kshar* and *Apamarga Pratisarneeya Kshar* in the management of *Ardra Arsha* (Internal Hemorrhoid)

- Dr. Himadri Mudgal- A comparative clinical study of Vasa Pratisaraniya Teekshna Kshar And Apamarga Pratisaraniya Teekshna Kshara in the management of Ardra Arsa (Internal Hemorrhoid)

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- Dr. Vineet Kumar Jain-A Clinical Study on the Efficacy of *Mridu, Madhyama* and *Teekshna Apamarga Pratisaraniya Kshar* in the management of *Ardra Arsha* (Internal Hemorrhoid)". – 2017

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- Laxmikant S.D.-Clinical evaluation of different application forms of Apamarga Kshar

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LITERATURE REVIEW

Literature will be collected related to Hemorrhoids from various books, articles and others sources.

RESEARCH QUESTIONS

Which is the most effective Procedure among *Apamarga Pratisaraniya Teekshna Kshar,* Laser Hemorrhoidopexy and Pile Suture Techniques in the management of *Ardra Arsha?*

STATEMENT OF HYPOTHESIS

Null Hypothesis –

There is no difference in the efficacy of *Apamarga Pratisaraniya Teekshna Kshar*, Laser Hemorrhoidopexy and pile suture technique in the management of *Ardra Arsha.*

Alternate Hypothesis –

There is difference in the efficacy of *Apamarga Pratisaraniya Teekshna Kshar,* Laser Hemorrhoidopexy and pile suture technique in the management of *Ardra Arsh*

AIM & OBJECTIVES

AIM

- To adjudge the best treatment modality among *Apamarga Pratisaraniya Teekshna Kshar*, Laser Hemorrhoidopexy Pile Suture Technique in *Ardra Arsha* (Second and Third degree Internal Hemorrhoid).

OBJECTIVES

- To analyses the different surgical and Para- surgical procedures mentioned in classical and contemporary science for the management of *Ardra Arsha* (Second and third degree internal hemorrhoid)
- To study the preparation of *Apamarge Pratisaraniya Teekshna Kshar* as per classical text.
- To compare the efficacy of *Apamarga Pratisaraniya Teekshna Kshar*, Laser Hemorrhoidopexy and pile suture technique in the management of *Ardra Arshas.*
- To compare the effect of *Apamarga Pratisaraniya*, *Teekshna Kshar*, laser Hemorrhoidopexy and pile suture technique in the management of *Ardra Arshas.*

MATERIALS AND METHODS

Total sample size - 120

Grouping - 3 Group (40 Patient in each group)

Allocation - Patients will be randomly allocated as per Computer generated randomization chart.

Source of subjects - OPD / IPD of P.G. Department of *Shalya Tantra*, National Institute of Ayurveda deemed to be University Jaipur.

Informed consent

The study will be explained clearly to the subjects and their informed written consent will be taken before starting of the trial.

Study Design

- Interventional
- Prospective
- Arms
- Randomized comparative clinical trial

STUDY PLAN

Total 120 participants will be selected after details examination and divided in 3 group of 40 patients each as per study protocol. all Procedures will be executed done under local anaesthesia. Post-operative treatment will be given as per study protocol. Patient will be taken for follow-up initially every week up to 28 days than every 15 days up to 3 months.

SELECTION CRITERIA

Inclusion Criteria

- Patients of Internal *Ardra Arsha* between the age group of 30 - 60 years.
- Patients of Internal Hemorrhoid which are *Mridu, Prasrita, Avagada* (Deep) and *Uchchhrita* (Projected).
- Patients of Internal Hemorrhoid having *Pittaja* and *Raktaja* origin.
- Diagnosed case of Internal Hemorrhoid of second, third degree.
- When patient is not responding to Ayurveda classical conservative treatment.

Exclusion criteria

- Patients with other systemic illnesses like uncontrolled Diabetes mellitus, Hypertension, Malignancy, Hepatitis B, Tuberculosis and Retrovirus positive.
- Infective and Neoplastic conditions of rectum, Rectal prolapse.
- Pelvic pathology and Pregnancy.
- Patient not fit for anesthesia.
- Fourth degree and with external component

Primary outcome

To Adjudge the Effective Intervention for Hemorrhoids

Secondary outcome

Changes in Grading of assessment criteria

STUDY SUBJECT

Participants attending the OPD and IPD of the NIA hospital and satisfying the selection criteria will be selected. All the participants who voluntarily agree to participate and provide informed written consent for participation will be recruited in the study.

CRITERIA FOR ASSESSMENT

Subjective Criteria

- ✓ *Ruja* (Post-Operative During defecation pain and rest pain) through Visual Analogue Scale
- ✓ Prolapse
- ✓ Pruritis
- ✓ Recovery time.
- ✓ Patient satisfaction (Quality of life).

Objective Criteria

- ✓ *Rakta Srava* (Bleeding amount and frequency) through counting of blood drops
- ✓ Duration of operative procedure
- ✓ Discharge
- ✓ Size of the pile mass.
- ✓ Anal sphincter tonicity (By Prof. Hemantha Kumar modified Sphincterometer
- ✓ Time to return to work.

Criteria for total assessment of procedure

Good Response	**:** Complete relief in presenting signs and symptoms of the disease.
Fair Response	**:** 75% and above relief of signs and symptoms.
Poor response	**:** 50% - 74% relief of signs and symptoms.
No Response	**:** Less than 50% Or No response in presenting signs and symptoms of disease.

Complication

During all procedure complications (Incontinence, Infection, Abscess, Re-occurrence Etc.) will be noted in each group and manage as per standard protocol.

Withdrawal Criteria (Any of the Following)

- ❖ Consent withdrawn by the participant or request by the participant.
- ❖ Serious adverse events/reactions where continuation of the study poses a serious risk to the participant.
- ❖ Need to use any drugs during study, which may interfere with assessment or influence the outcome.
- ❖ Development of clinical conditions which lead to violation of Inclusion/ Exclusion criteria.
- ❖ In case of withdrawals or dropouts, the investigator will assess the participant clinically and the reason for discontinuation from the study will be entered into the CRF.

STUDY DESIGN

Number of Subjects	120 participants
Population to be Studied	Subjects from either Gender
Allocation	Not Applicable
Endpoint Classification	Efficacy Study
Intervention	Pile Suture Technique, Laser Hemorrhoidopexy and *Apamarga Pratisaraniya Teekshna Kshar* Application
Duration of Trial	Total duration of trial is 28 days
Follow Up	3 Months
Study Design	Interventional, Comparative, 3 Arms, Prospective
Time Frame	Trial with follow up period
Assessment	On 1st, 2nd ,3rd and 4th weak then every 15 days for next 3 months

Arms	Assigned Intervention
Group A	**Procedure:** *Apamarga Pratisaraniya Teekhshna Kshar* application. The procedure will be done under local anesthesia. The *Apamarga Kshar* will be applied on individual Internal Hemorrhoids mass until itturns *Pakwa Jambuphala Varna* and then it will be washed out with *Nimbu Swarasa* and Normal Saline.
Group B	**Procedure:** Laser Hemorrhoidopexy procedure will be done under local anesthesia The Lesser probe will be applied on each Internal Hemorrhoids mass until it coagulates.
Group C	**Procedure:** Pile suture technique procedure will be done under Local anesthesia. After painting and draping holding of internal Hemorrhoids with Babcock forceps and ligation and trans fixation of each internal Hemorrhoid is to be done with the help of number-1 chromic catgut with round body atraumatic needle.

TREATMENT RECOMMENDATIONS:

Pre – Operative Treatment

Prophylaxis Tetanus Toxoid (0.5 ml Intramuscular) will be given before surgery.

Prophylaxis one shot of antibiotic (Inj. Ceftriaxone – 1 gm. Intravenous) will be given 2 hours before surgery after Sensitivity test.

Operative Procedures

Anesthesia

All procedure is to be done under local anesthetic agent after check of sensitivity (Injection lignocaine with adrenaline 1%solutions).

Anesthesia dose will be calculated as per standard dose 5-7 mg/kg body weight

If patient is not cooperated with local anesthesia then he/she can be planed for spinal anesthesia (Lignocaine 5%).

PROCEDURES

***Apamarga Pratisaraniya Teekshna Kshar* Application:**

The patient will be placed in a lithotomic position on the operation table and the perianal area will be cleaned with aseptic solutions. Then draping will be done with a sterilized cut sheet. After that local infiltration anesthesia will be given. With the help of lignocaine (Gel) smeared *Arshoyantra* (Slit Proctoscope), pile masses will be re-assessed for their numbers, positions and sizes. One pile mass ata time will be selected. The pile mass will be scraped or rubbed and cleaned with cotton swab soakedwith warm water. Then the *Apamarga Kshar* will be applied over the pile mass with the help of *Darvimukha Shalaka* under direct vision. As soon as applying the *Kshar*, the opening of the *Arsho Yantra* will be closed by cotton swab and wait for a period of a hundred *Matra Kala.* When the colour of pile mass is looked like *Pakwa Jambu Phala,* the *Apamarga Kshar* will be washed out with freshly prepared *Nimbu Swarasa*. Later the anal packing will be done with *Yashtimadhu Taila Pichu.* All the pile masses will be applied in a single sitting.

Procedure of Laser Hemorrrhoidopexy

Laser probe (Bare fiber) introduce surface through anoderm and inserted by sub mucosal plane till away to 2 cm away from Hemorrhoids cushions and the energy (150-350 Joule) per segments delivered insight

the venous plexus. Moving the tip sidewise is very important for even distribution laser energy into tissue than applied ice after delivered of each anal cushion.

Pile Suture Technique

The procedure will be performed with the patient in lithotomy position under local anaesthesia. Anal dilatation will be done up to 2-3 fingers in each patient before starting of procedure. This relieves the spasm and helps in minimization of thrombosis and postoperative pain. Namely Hemorrhoids present at 3, 7 and 11 o'clock positions will be hold and retract out to visualize the Hemorrhoid mass withthe help of Babcock forceps, number 1 chromic catgut of 40mm with atraumatic needle is to be used, then the whole pile mass will be hold under and transfixed from above to downwards with interruptedsutures. If the pile mass was found to be too big, then the suture was locked and tied in the middle and a fresh under running began, the final stitch reaching just below the pile mass and including the normal rectal mucosa. The initial suture line occludes the connection between the internal and external Hemorrhoids plexus and the inner half occludes the hemorrhoid vessels.

Post-Operative Treatment

- ✓ Proper Analgesia (Diclofenac Sodium 75mg Intramuscular/ 50mg oral) will be given as per requirement.
- ✓ Antiemetic drugs (Injectable /oral) will be given if needed.
- ✓ *Triphala Guggulu* 500 mg. twice daily after meal for 7 days
- ✓ Laxative- *Triphla Churna* 5 gm. at bedtime for 7 days with lukewarm water.
- ✓ Warm Sits bath by *Tankan Bhasma* 1/2 tsf - twice daily for 7 days
- ✓ *Yasthimadhu Taila Matra Basti* 15 ml. twice daily for 7 days in case of *Kshar* application.
- ✓ *Yasthimadhu Taila* for P/R *Pichu* twice daily for 7 days in case of *Kshar* application.
- ✓ Foley catheter is to be applied in case of retention of urine.

DRUG REVIEW

Ingredients of *Apamarga Teekshna Kshar*

S. No.	Dravya	Botanical Name	Used Part	Marta
1.	*Apamarga Ash*	*AchyranthesAspera*	*Panchang*	1
2.	*Chitraka*	*Plumbago Zeylanica*	*Mool*	1/100
3.	*Shukti*	Oyster Shell	Shell	1/10

LAB INVESTIGATIONS

CBC, ESR, CT-BT, HIV, HbsAg, RBS, RFT, LFT, Urine R/M, ECG, Chest X-ray,
RTPCR for Covid-19 (If needed)

RESULTS:

Results of the treatment will be tabulated and analyzed statistically with relevant tests and level of significance will be reported as per guidance of statistician.

Unscheduled Visits

A participant may visit the study site on some other day if required due to adverse effects/complications or if symptoms not getting resolved. The participant will contact the study coordinator for the same. This visit will be called as unscheduled visit. All the information will be captured at the unscheduled visit and documented

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PROPOSED CONTENT OF DISSERTAATION: -

All the observations recorded and results obtained will be computerized statistically to draw various conclusions. The project will be presented in the form of a thesis with following contents-

- Acknowledgement
- Introduction
- Re-view of literature
  - Classical review
  - Modern review
  - Drug review
- Materials and Methods
  - Clinical and Conceptual study
- Observations and Results
- Discussions and Conclusion
- Summary
- Bibliography
- Appendix

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